

METHOD OF DIAGNOSING AND MONITORING
MALIGNANT BREAST CARCINOMAS

09/914501

This application is a Continuation-in-Part of U.S. Application No. 09/259,993 filed March 1, 1999 and claims priority benefit therefrom.

Background of the Invention.

This invention relates generally to the use of salivary biomarkers to diagnose breast cancer and, more particularly, to diagnostically differentiate between women with carcinoma of the breast, women with benign tumors, and healthy controls.

Breast cancer is the second leading cause of death among women in the United States. Approximately 1 woman in every 10 will develop breast cancer in her lifetime. Recent statistics estimate that 44,000 women will die of breast cancer, while 150,000 new female cases of breast cancer will be diagnosed in the next year.

It has been shown that screening for breast cancer can reduce breast cancer mortality. Among women aged 50 and older, studies have demonstrated a 20% to 40% reduction in breast cancer mortality for women screened by mammography and clinical breast examination. However, among women between 40 to 49 years of age, the mortality rate is reduced only 13% to 23%. These results suggest that further methods of screening could potentially reduce the mortality in the younger age group of women.

While physical examination and mammography are useful screening procedures for the early detection of breast cancer, they can produce a substantial percentage of false positive and false negative results especially in women with dense parenchymal breast tissue. For example, the probability of having a false negative mammographic examination is 20% to 25% among women between 40 to 49 years of age and 10% among women 50 to 69 years of age. Consequently, screening will result in a number of negative biopsy results yielding a high percentage of false positives. There is also a demonstrated lack of sensitivity in detecting cancerous lesions in younger women yielding a significant percentage of false negatives.

There has also been a clear need for added modalities of screening to help diagnose cancer in younger women. Increased technology in the field of mammography has allowed more reliable detection of small lesions of the breast; while, researchers in the field of breast cancer continue to seek additional adjunct diagnostic procedures to further enhance cancer screening and, thereby, to reduce mortality rates.

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